



## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Billot et al.

Serial No. 10/797,257

Art Unit: 1614

Filed: March 10, 2004

Examiner: To be AssignedFor: EP4 Receptro Agonist , Compositions and Methods  
ThereofCommissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450INFORMATION DISCLOSURE STATEMENT  
UNDER 37 CFR 1.97

Sir:

1. In compliance with 37 C.F.R. 1.97, submitted on the attached form herewith is a list of patents, publications or other information which are requested to be made of record in this application. This Information Disclosure Statement is not an admission that any patent, publication or other information referred to herein is "prior art" for this invention. In accordance with 37 C.F.R. 1.97(h), the filing of this Information Disclosure Statement shall not be construed to be an admission that the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. 1.56(b).

2. In accordance with 37 C.F.R. 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made.

3. Applicants respectfully request that the Examiner initial the attached form after reviewing the pertinence of each reference.

4. Pursuant to the waiver by the Office of the requirement under 37 CFR 1.98 (a)(2)(i) dated July 11, 2003, if the filing date of this application is after June 30, 2003, copies of each cited U.S. patent and each U.S. patent application publication are not enclosed herewith.

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450, on the date appearing below.

By *[Signature]* **MERCK & CO., INC.** Date 10/12/2004

**INFORMATION DISCLOSURE STATEMENT**

5. Pursuant to 37 C.F.R. 1.98(d), copies of references listed on the attached form that were submitted to or cited by the Office in a related application upon which the instant application relies for an earlier filing date under 35 U.S.C. 120 are not enclosed. Related application(s) in which references were submitted to or cited by the Office are as follows:

| RELATED APPLICATION |             |            |
|---------------------|-------------|------------|
| U. S. SERIAL NUMBER | FILING DATE | MERCK CASE |
|                     |             |            |
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If this is inconvenient, additional copies will be submitted upon request.

6. In accordance with 37 C.F.R. 1.97, (check one)

- ☐ the attached information is filed within three months of the filing date of the captioned case.
- ☒ the attached information is filed more than three months after the filing date but prior to the mailing of a first Office Action on the merits.
- ☐ the attached information is being filed more than three months after the filing date and after the mailing of a first Office Action on the merits, but before the mailing date of a Final Action or Notice of Allowance. The enclosed authorization is therefore given to charge Deposit Account No. 13-2755 for the fee required under 37 C.F.R. 1.17(p).
- ☐ the undersigned certifies that each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Statement.
- ☐ the undersigned certifies that no item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, was known to any individual designated under 37 C.F.R. 1.56(c) more than three months prior to the filing of this Statement.

Respectfully submitted,

By: Sylvia A. Ayler

Attorney For Applicant(s)

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MERCK & CO., INC.

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Date: October 12, 2004

**COMPLETE IF KNOWN**

|                             |                |
|-----------------------------|----------------|
| <b>Application Number</b>   | 10/797,257     |
| <b>Filing Date</b>          | March 10, 2004 |
| <b>First Named Inventor</b> | Billot et al.  |
| Group Art Unit              | 1614           |
| Examiner Name               | To be Assigned |
| Attorney Docket Number      | MC080Y         |

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|                        |        |
|------------------------|--------|
| Attorney Docket Number | MC080Y |
|------------------------|--------|

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| Examiner Initials* | Cite No. | Foreign Patent Document |              |                         | Name of Patentee or Applicant of Cited Document | Date of Publication of Cited Document<br>MM-DD-YYYY |
|--------------------|----------|-------------------------|--------------|-------------------------|---|---|
|                    |          | Office                  | Number       | Kind Code<br>(if known) |   |   |
|                    |          | K.                      | WO 02/24647  | A1                      | Ono Pharmaceutical                              | 03/28/2002  |
|                    |          | L.                      | WO 02/42268  | A2                      | Pfizer Products Inc.                            | 05/30/2002  |
|                    |          | M.                      | EP 1114816   | A1                      | Ono Pharmaceutical                              | 07/11/2001  |
|                    |          | N.                      | WO 01/46140  | A1                      | Pfizer Products Inc.                            | 06/28/2001  |
|                    |          | O.                      | WO 03/105868 | A1                      | Merck & Co. Inc.                                | 12/24/2003  |
|                    |          | P.                      | WO 03/105724 |                         | Merck & Co. Inc.                                | 12/24/2003  |
|                    |          | Q.                      | WO 03/105847 | A1                      | Merck & Co. Inc.                                | 12/24/2003  |
|                    |          | R.                      | WO 02/060863 | A1                      | Merck & Co. Inc.                                | 08/08/2002  |
|                    |          | S.                      | GB 1 524 818 |                         | Beecham Group Ltd.                              | 11/29/1974  |
|                    |          | T.                      | WO 01/72268  | A2                      | Merck & Co.                                     | 10/03/2002  |

Date Considered

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of

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## Application Number

**Filing Date****First Named Inventor**

## Group Art Unit

Examiner Name

Attorney Docket Number

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| Examiner Initials* | Cite No. | Foreign Patent Document |              |                         | Name of Patentee or Applicant of Cited Document | Date of Publication of Cited Document<br>MM-DD-YYYY |
|--------------------|----------|-------------------------|--------------|-------------------------|---|---|
|                    |          | Office                  | Number       | Kind Code<br>(if known) |   |   |
|                    | U.       |                         | WO 94/13275  | A1                      | Massachusetts Eye and Ear Infirmary             | 06/23/1994  |
|                    | V.       |                         | WO 01/70702  | A1                      | Alcon Universal Ltd.                            | 09/27/2001  |
|                    | X.       |                         | WO 00/21542  | A1                      | Merck & Co. Inc.                                | 04/20/2000  |
|                    | Y.       |                         | EP0855389    | B1                      | Ono Pharmaceutical                              | 01/26/1998  |
|                    | Z.       |                         | WO 03/047417 | A2                      | Merck & Co. Inc.                                | 06/12/2003  |
|                    | AA.      |                         | WO 03/047513 | A2                      | Merck & Co. Inc.                                | 06/12/2003  |
|                    | BB.      |                         | EP 0 008 186 | A1                      | Beecham Group Limited                           | 07/30/1979  |
|                    | CC.      |                         | WO 02/077168 | A2                      | Merck & Co. Inc.                                | 10/03/2002  |
|                    |          |                         |              |                         |   |   |
|                    |          |                         |              |                         |   |   |

Examiner  
Signature

Date Considered

\*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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|---|---|----|--------------------------|------------------------|--------|
| Substitute for form 1449B/PTO<br><b>INFORMATION DISCLOSURE</b><br><br><b>STATEMENT BY APPLICANT</b><br><br><i>(use as many sheets as necessary)</i> |   |    | <b>COMPLETE IF KNOWN</b> |                        |        |
|   |   |    | Application Number       | 10/797,257             |        |
|   |   |    | Filing Date              | March 10, 2004         |        |
|   |   |    | First Named Inventor     | Billot et al.          |        |
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|   |   |    | Examiner Name            | To be Assigned         |        |
| Sheet   | 3 | of | 3                        | Attorney Docket Number | MC080Y |

| NON PATENT LITERATURE DOCUMENTS |          |   |
|---------------------------------|----------|---|
| Examiner Initials*              | Cite No. | Include name of the author, title, date, page(s), volume-issue number(s) and place of publication.  |
|                                 | DD.      | P. Barraclough et al., "Heterocyclic Prostaglandin Analogues. Part 4, Piperazine-2,5-diones, Pyrazolidine-3,5-diones, 1,2,4-Triazolidinediones, 1,3,4-Oxadiazolidine-diones and 1,3,4-Thiadiazolidinediones", 1980, pp. 2096-2105, J.C.S. Perkin I. |
|                                 | EE.      | R. A. Schumer et al., "The Nerve of Glaucoma", 1994, pp. 37-44, Vol. 112, Arch Ophthalmol.  |
|                                 | FF.      | M. Weinreb et al., "Different Pattern of Alkaline Phosphatase, Osteopontin, and Osteocalcin Expression in Developing Rat Bone Visualized by in Situ Hybridization", 1990, Vol. 5, No. 8, J. of Bone and Mineral Research.                           |
|                                 | GG.      | D. A. Dartt et al., "Localization of Nerves Adjacent to Goblet Cells in Rat Conjunctiva" 1994, pp. 993-1000, Vol. 14, Curr. Eye Res.  |
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|                                 | II.      | E. M. Ross, "Mechanisms of Drug Action and the Relationship Between Drug Concentration and Effect", pp. 29-41, chapter 2, Goodman and Gilman's Pharmacological Basis of Therapeutics.   |
|                                 | JJ.      | I. K. Gipson et al., "Mucin Genes Expressed by the Ocular Surface Epithelium", 1997, pp. 81-98, Vol 16, No. 1, Progress in Retinal and Eye Research.  |
|                                 | KK.      | D. M. Shinar et al., "Expression of alphaV and Beta Integrin Subunits in Rat Osteoclasts in Situ", 1993, pp. 403-414, Vol. 8, No. 4, J. of Bone and Mineral Research.   |
|                                 | LL.      | M. A. Lemp et al., "Report of the National Eye Institute/Industry Workshop on Clinical Trials in Dry Eyes", 1995, pp. 221-232, Vol. 21, No. 4, CLAO Journal.  |
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|                                 | NN.      | P. Chomczynski et al., "Single-Step Method of RNA Isolation by Acid Guanidinium Thiocyanate-Phenol-Chloroform Extraction", 1987, pp. 156-159, Vol. 162, Analytical Biochemistry.  |
|                                 | OO.      | S.B. Rodan et al., "Growth Stimulation of Rat Calvaria Osteoblastic Cells by Acidic Fibroblast Growth Factor", 1987, pp.1917-1923, Vol. 121, No. 6, Endocrinology.  |
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|--------------------|--|-----------------|--|
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